

## **I. REMARKS**

### **A. Status of the Claims**

Claims 1-21, 23-35, 37, 39, and 42 were pending in the case at the time of the Office Action. Claims 1, 9, 17, 19, 23, 29, 35, 39, and 42 have been amended in the Amendment set forth herein. No new claims have been added. Thus, claims 1-21, 23-35, 37, 39, and 42 are currently under consideration.

Non-limiting examples of support for the amendments of the claims to concern “backscattered” light can be found generally throughout the specification, such as in the claims as originally filed and on page 5, line 19; page 6, lines 1-3; page 6, lines 21-22; page 7, lines 7-9; page 25, lines 1-14; and the working examples. Non-limiting examples of support for “maximum intensity” can be found on page 6, line 23 – page 7, line 5; and page 36, line 12 – page 37, line 3.

### **B. The Rejections Under 35 U.S.C. §103(a) Are Overcome**

#### **1. Rejections Based on Dreher in View of Hay and Further in View of Glaser and/or Larrick**

Claims 1-5, 6-14, 15-19, and 23-24 are rejected under 35 U.S.C. §103(a) as being unpatentable over Dreher *et al.* (U.S. Patent 5,303,709; hereinafter “the Dreher patent”) in view of Hay *et al.* (U.S. Patent 5,632,282; hereinafter “the Hay patent”) and further in view of Glaser *et al.* (U.S. Patent 5,767,079; “the Glaser patent”) and/or Larrick *et al.* (U.S. Patent 5,670,151; “the Larrick patent”). The Examiner argues that it would be obvious to one of ordinary skill in the art at the time the invention was made to combine these references to lead to the claimed invention. In particular, the Dreher patent is said to teach each limitation of the claimed invention except a tissue sample holder and neovascularization, but that the Glaser, Hay, and/or

Larrick patents provide motivation to modify the Dreher patent to include these limitations. Applicants respectfully traverse.

***a. The Cited References Fail to Provide for Measurement of Any Physical Property of Backscattered Light***

It is noted that the method claims as amended (claims 1 – 34) include a limitation involving measurement of a particular physical property of a backscattered light beam (such as maximum intensity and/or polarization shift). The apparatus claims as amended (claims 35 – 42) require a data acquisition system configured to measure a particular physical property of a backscattered light beam.

The presently claimed methods and apparatuses are distinct from those set forth in the cited prior art patents because none of the cited prior art patents concern any method that involves analysis of a physical property of backscattered light or an apparatus configured to analyze a physical property of backscattered light. Applicants herein submit the Declaration of Dr. Andrew Tsin (Exhibit 1, hereinafter “the Declaration”), one of the present inventors, to explain the differences between the cited prior art and the instant invention. He notes in ¶6 of his Declaration that the Dreher patent specifically concerns methods and devices for measuring the topography and thickness of the nerve fiber layer that involve measuring the polarization shift of a *reflected* probing light. See abstract, FIG. 1, and col. 2, lines 60-68. Thus, rather than measurement of properties of backscattered light, the Dreher patent is *distinct* because it concerns measurement of a physical property of reflected light. The Hayes patent concerns methods for diagnosing eye disease that involve measurement of light *reflected* from a patient’s retina. The Larrick patent does not concern ophthalmic imaging, but instead concerns methods of controlling hyperproliferative disease of the integument and the eye. The Glaser patent does not concern optical diagnosis, but instead concerns an ophthalmic treatment method employing

Transforming Growth Factor  $\beta$ . Thus, none of the cited prior art patents are relevant to the claimed invention since they do not concern analysis of backscattered light.

There are fundamental differences between reflected light and backscattered light. These differences are explained by Dr. Tsin in ¶7 of his Declaration. He notes that the fundamental differences between these two types of light and matter interactions can be characterized by where the interaction of light and matter occurs, known physical laws which govern the interaction, and the types of interactions between light and matter that occur during these processes. In the most basic physical treatment, Dr. Tsin notes that reflection is defined as the return of incident electromagnetic radiation (*i.e.*, light) by a surface. This is discussed in references readily available to those in the field of the invention, such as on page 177 of Optics Source Book. Ed. Parker, Sybil P, 1988 McGraw-Hill, ISBN 0-07-045506-6 (Exhibit A of the Declaration) and page 79 of Optics. Hecht E, 1987 Addison-Wesley Publishing, ISBN 0-201-11609-X (Exhibit B of the Declaration). For an incident beam of light, Dr. Tsin notes that there exists a number of fundamental laws which describe how the direction of the light is changed by interaction with a “reflective” surface. The law of reflection states that the angle of incidence of light is directly equal to that of the reflected light (see Exhibit A and page 83 of Optics cited above (Exhibit C)). Reflectivity, or a direct measure of the amount of radiation reflected by a material, is dependent upon the angle of incidence, polarization state of incoming radiation, and the electromagnetic properties of the material.

In the case of scattered light, of which backscattered light is merely a special case where the angle of scattering is greater than 90 degrees, Dr. Tsin explains in ¶8 of his Declaration that the interaction between light and matter is approached from a microscopic point of view. Scattering is described as the removal of energy from an incident wave and the subsequent remission of some portion of that energy. This is discussed on page 293 of Optics cited above

(Exhibit D of the Declaration). Dr. Tsin further notes that the angle at which the scattered photon is remitted is highly dependent upon the type of scattering which it undergoes. In complex structures, such as tissue, there are often multiple scattering events from the time the photon enters the material to the time it exits the material. Thus, he notes that a photon which is scattered only once will have a different final direction than a photon which is scattered three or four times. This is said to be ultimately responsible for the statistical nature of scattered light in tissues. Thus, due to the optically non-homogenous properties of biological tissues, it is not uncommon to see reflection at the surface, as well as transmission and scattering through biomaterials (see page 3 of Tissue Optics, Tuchin V, 2000 SPIE Press, ISBN: 0-8194-3459-0 (Exhibit E of the Declaration)).

In the specific case of the present invention as discussed in ¶9 of the Declaration, backscattered light is light that is scattered in such a way that it finds its way back towards the light source and occurs at a range of depths into the tissue.

The Dreher patent does not concern backscattered light. As discussed by Dr. Tsin in ¶10 of the Declaration, the Dreher patent specifically states that the light reflected off of the posterior or anterior surfaces of the eye offers the method of detection (see Column 2 Line 64, Column 3 Line 9, Column 5 Line 1, Column 5 Line 47, Column 10 Line 14). In contrast, the present invention utilizes light which is backscattered throughout the entirety of a tissue layer. More so, it is clearly stated in the Dreher patent that the aim of the device is to determine optic nerve thickness by exploitation of the birefringence properties of that tissue (Column 3 Line 65 – Column 4 Line 20), whereas the present claimed invention seeks to determine degree of a pathological condition (neovascularization as exemplified by angiogenesis of retinal or choroidal capillaries). Thus, there are distinct differences between the methods and apparatuses of the

Dreher patent and the present invention. Given these differences, one of ordinary skill in the field of the invention would not have arrived at the claimed methods and apparatuses.

A finding of obviousness requires that “the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” 35 U.S.C. §103(a). In *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 82 U.S.P.Q.2d 1385 (2007), the Supreme Court stated that it is “important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the ways the claimed new invention does ....” *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741, 82 U.S.P.Q.2d 1385, 1396 (2007).

Here, Applicants do not identify any information in the cited patents would have prompted a person of ordinary skill in the field of the invention to lead to the presently claimed invention. None of the cited references concern analysis of a physical property of backscattered light. Therefore, there is no basis for a *prima facie* case of obviousness.

***b. The References Cited by the Examiner Teach Away from the Presently Claimed Invention and Do Not Provide Any Reasonable Expectation of Success to Practice the Claimed Invention***

To the extent that the cited prior art patents actually emphasize analysis of reflected light and omit discussion of backscattered light, they actually teach away from the presently claimed invention. As a group, the cited patents emphasize analysis of reflected light rather than backscattered light.

Further, the apparatuses described in the Dreher patent require use of a “corneal polarization compensator.” See abstract. The present invention does not involve use of a corneal polarization compensator. As discussed by Dr. Tsing in ¶11 of the Declaration, use of this additional component in the context of the present invention would result in loss of information

in that it would likely result in loss of some portion of backscattered light. Therefore, one of ordinary skill in the field would not be likely to successfully practice the claimed methods of diagnosing an ocular disease involving neovascularization with the apparatuses of the Dreher patent.

Thus, as concluded by Dr. Tsin, “[g]iven the fundamental differences between the light that is being measured in the Dreher patent (and other cited patents) and the present invention and the requirement for a corneal polarization compensator in the Dreher patent, a person with training in ophthalmic imaging and optics would not have been motivated to modify the Dreher patent or combine it with any of the other references cited by the Examiner to result in the claimed methods and apparatuses. None of the references cited by the patent examiner concern analysis of backscattered light, which is the heart of the present invention.”

In view of the foregoing, claims 1-5, 6-14, 15-19, and 23-24 are not unpatentable over the Dreher patent, the Hay patent, the Glaser patent, and/or the Larrick patent. Therefore, it is respectfully requested that the rejection of these claims under 35 U.S.C. §103(a) be withdrawn.

## **2. Rejections Based on Dreher in View of Hay and Further in View of Trachtman**

Claims 20-21, 35, 37, 39, and 42 are rejected under 35 U.S.C. §103(a) as being unpatentable over the Dreher patent in view of the Hay patent as applied above, and further in view of the Trachtman patent (U.S. Patent 5,002,384). Applicants respectfully traverse.

As set forth in the foregoing section (the discussion of which is herein incorporated into this section), there is no *prima facie* case of obviousness based on the Dreher patent in view of the Hay patent. As set forth by Dr. Tsin in ¶12 of his Declaration, given the “fundamental differences” between the light that is being measured in the Dreher patent (“reflected light”) and the present invention (“backscattered light”) and the requirement for a corneal polarization

compensator in the Dreher patent, a person of ordinary skill in the field would not have been motivated to modify the Dreher patent or combine it with the Hay patent to lead to the claimed methods and apparatuses.

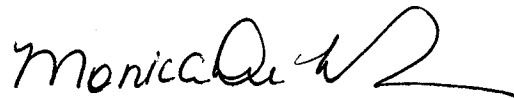
Further, the Trachtman patent fails to provide for motivation to modify the Dreher and Hay patents to lead to the claimed invention. As discussed by Dr. Tsin in ¶6 of the Declaration, the Trachtman patent concerns analysis of infrared light *reflected* from the patient's cornea and retina for monitoring and training eye position. It does not concern analysis of backscattered light. *Id.* Therefore, the Trachtman patent fails to remedy the deficiencies of the Dreher patent and the Hay patent.

In view of the foregoing, there is no *prima facie* case of obviousness of claims 20-21, 35, 37, 39, and 42 under 35 U.S.C. §103(a) based on the Dreher patent and the Hay patent in view of the Trachtman patent. Therefore, it is respectfully requested that the rejection of these claims be withdrawn.

### **C. Conclusion**

In view of the foregoing, it is respectfully submitted that each of the pending claims is in condition for allowance, and a Notice of Allowance is earnestly solicited. The Examiner is invited to contact the undersigned attorney at (512) 536-5639 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



Monica A. De La Paz  
Reg. No. 54,662  
Attorney for Applicants

FULBRIGHT & JAWORSKI L.L.P.  
600 Congress Avenue, Suite 2400  
Austin, Texas 78701  
512.474.5201 (telephone)  
512.536.4598 (fax)

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